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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,812	12/08/2005	Kazuyuki Oku	OKU11	7345
1444 7590 10/17/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER BLAND, LAYLA D	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 10/17/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/559,812	Applicant(s) OKU ET AL.	
	Examiner Layla Bland	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This application is a national stage entry of International Application No. PCT/JP04/08105, filed June 6, 2004, and claims priority to Japanese Application No. 164886/2003, filed June 10, 2003. Claims 1-26 are pending in this application and are examined on the merits herein.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 (and dependent claims), 13 (and dependent claims) and 18 (and dependent claims) recite the limitation "associated complex." It is unclear what constitutes "an associated complex" and what the complex is associated with.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 13-16, 18-22, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida et al. (US 6,159,529, December 12, 2000) in view of Maruta et al. (US 6,017,899, January 25, 2000).

Uchida et al. teach that trehalose-containing agents enhance the level of salty or delicious taste and can be substituted for conventional seasonings such as table salt [column 5, lines 38-41]. Usually the food products contain trehalose in amount of at least 1.5 w/w% and sodium chloride should be present in an amount of at least 1.5% [column 3, lines 16-33]. Trehalose can be used with mineral-enriching agents such as calcium chloride [column 5, lines 50-57]. A solution of sodium chloride and trehalose was prepared in water and it was found that trehalose enhanced the salty taste of the solution [column 6, lines 15-67]. A table salt like agent was prepared from 80 parts by weight of trehalose, 10 parts by weight of potassium chloride, 7 parts by weight of calcium chloride, and 3 parts by weight magnesium sulfate [column 14, lines 14-33]. This composition has a salty taste and supplies calcium and magnesium, which would be beneficial to patients with circulatory disease [column 14, lines 14-33].

Uchida et al. do not teach a composition comprising a complex of an  $\alpha$ -glycosyl  $\alpha,\alpha$  trehalose and a metal ion compound.

Maruta et al. teach non-reducing saccharides ( $\alpha$ -glucosyl trehalose,  $\alpha$ -maltosyl trehalose,  $\alpha$ -maltotriosyl trehalose,  $\alpha$  maltotetraosyl trehalose and  $\alpha$ -maltopentaosyl trehalose [column 19, lines 42-53]) which can be used as taste-improving agents, quality-improving agents, stabilizers, excipients and dessicants in food products and other products [column 12, lines 32-38]. They have a sweetness which harmonizes well

with materials having salty tastes and are highly acid- and heat-resistant [column 12, lines 59-67].

It would have been obvious to one of ordinary skill in the art to prepare a complex comprising an  $\alpha$ -glycosyl  $\alpha,\alpha$  trehalose and a metal ion compound. Metal-trehalose complexes are known to enhance the salty taste of foods and  $\alpha$ -glycosyl  $\alpha,\alpha$  trehalose compounds are known to be useful as taste-improving agents which harmonize well with salty tastes. The skilled artisan could combine these two teachings to arrive at a mineral supplement that could easily be predicted to be a taste-improving agent for salty foods.

Claims 9-12, 17, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida et al. (US 6,159,529, December 12, 2000) in view of Maruta et al. (US 6,017,899, January 25, 2000) as applied to Claims 1-8, 13-16, 18-22, and 24-26 above, and further in view of Cook et al. (Carbohydrate Research, 31 (1973) 265-275).

Uchida et al. and Maruta et al. teach as set forth above.

Neither Uchida et al. nor Maruta et al. teach a crystalline complex of an  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose and a metal ion compound.

Cook et al. teach crystalline  $\alpha,\alpha$ -trehalose-calcium bromide [see abstract]. The crystals were obtained by evaporating an aqueous solution that contained an approximately equimolar mixture of  $\alpha,\alpha$ -trehalose and calcium bromide [page 266,

Experimental]. In the crystal structure of the complex, the calcium ion is surrounded by a coordination polyhedron composed of seven oxygen atoms [page 269, last sentence].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising a crystalline complex of an  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose and a metal ion compound. Such a complex has predictably desirable properties, as discussed above, and the skilled artisan would be motivated to crystallize the complex in order to obtain a product of superior purity. The skilled artisan would have an expectation of success because a complex of  $\alpha,\alpha$ -trehalose with calcium bromide has been crystallized before, as taught by Cook et al. The skilled artisan would understand that a calcium chloride complex could be prepared using the guidance provided by Cook et al. for the preparation of a calcium bromide complex.

Claims 1-8, 13-16, 18-22, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oku et al. (WO 03/016325 A1, February 27, 2003, using the English language equivalent US 2004/0209841, October 21, 2004) in view of Maruta et al. (US 6,017,899, January 25, 2000).

Oku et al. teach associates of trehalose and metal compounds which have improved deliquescence, reducing power, oxidizing power, and solubility [see abstract]. The associates are formed by mixing trehalose with metal ion compounds in a solvent such as water or in solid forms [0027]. A crystalline associate was formed from one mole of calcium chloride dehydrate and one mole of trehalose in aqueous solution [0067 and 0068]. The resulting compounds have improved deliquescence, which gives them

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good handleability on preserving or admixing with various compositions [0163].

Magnesium and calcium are required for enzymatic reactions in human bodies but metal ion compounds taste unpleasant [0003 and 0004].

Oku et al. do not teach a composition comprising a complex of an  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose and a metal ion compound.

Maruta et al. teach non-reducing saccharides ( $\alpha$ -glucosyl trehalose,  $\alpha$ -maltosyl trehalose,  $\alpha$ -maltotriosyl trehalose,  $\alpha$ -maltotetraosyl trehalose and  $\alpha$ -maltopentaosyl trehalose [column 19, lines 42-53]) which can be used as taste-improving agents, quality-improving agents, stabilizers, excipients and dessicants in food products and other products [column 12, lines 32-38]. They have a sweetness which harmonizes well with materials having salty tastes and are highly acid- and heat-resistant [column 12, lines 59-67].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising a crystalline complex of an  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose and a metal ion compound. Metal-trehalose complexes are known to be useful in food compositions which contain calcium and  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose compounds are known to be taste-improving agents. The skilled artisan could combine these two teachings to arrive at a food additive that could easily be predicted to be a taste-improving agent.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.



Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 14 of U.S. Patent No. 6,017,899 in view of Uchida et al. (US 6,159,529, December 12, 2000). The difference between the instant claims and those of U.S. Patent No. 6,017,899 is that the instant claims are drawn to complexes of  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose with a metal ion compound and the claims of U.S. Patent No. 6,017,899 are drawn to  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose compounds. However, Uchida et al. teach metal ion complexes of  $\alpha,\alpha$ -trehalose which have advantages as food additives, as do the currently claimed compositions, as discussed above. Thus, the instant claims are considered obvious over the claims of U.S. Patent No. 6,017,899.

Claims 1-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 and 38 of copending Application No. 10/486,328 in view of Maruta et al. (US 6,017,899, January 25, 2000) and Cook et al. (Carbohydrate Research, 31 (1973) 265-275).

The difference between the instant claims and those of copending Application No. 10/486,328 is that the instant claims are drawn to metal complexes of  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose with a metal ion compound and the claims of copending Application No. 10/486,328 are drawn to metal complexes of  $\alpha,\alpha$ -trehalose. However, Maruta et al. teach that  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose compounds have desirable properties as food

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additives, as do the currently claimed compositions, as discussed above, and Cook et al. teach crystallization of a  $\alpha,\alpha$ -trehalose -calcium ion complex. Thus, the instant claims are considered obvious over the claims of copending Application No. 10/486,328.

This is a provisional obviousness-type double patenting rejection.

### ***Conclusion***

No claims are allowed.

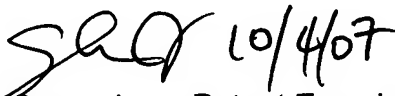
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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October 2, 2007

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